

REMARKS

The Office Action dated June 20, 2007 has been reviewed and the comments have been considered. Claims 1-16 are pending. Claims 1, 3, 5, 7, 10, and 11 have been amended. New claims 13-16 have been added. No new matter has been added by the present amendment. Applicants respectfully submit that the present application is in condition for allowance and such action is earnestly requested.

Claims 1-12 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants respectfully submit that the phrases pointed out by the Examiner permit Applicants to particularly point out and distinctly claim the subject matter of his invention with sufficient clarity and precision such that the threshold requirement of definiteness of claims 1-12 has been met. *See, MPEP § 2173.02 (Rev. 5, August 2006), which states that “[t]he Examiner’s focus during examination ...with the requirement of 35 U.S.C. 112, second paragraph is whether the claims meet the threshold of clarity and precision, not whether more suitable language or modes of expression are available.”* However, in an effort to expedite prosecution, applicants have amended claims 1, 3, 5, 7, 10, and 11 in accordance with the Examiner’s suggestions. Accordingly, this rejection should be withdrawn.

Claims 1-3, 5-7, 10, and 11 stand rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 6,299,838 to Hirayama et al (Hirayama). Claims 1-12 stand rejected under 35 U.S.C. § 103 as being unpatentable over Hirayama in view of U.S. Patent No. 5,843,692 to Philips et al., (Phillips), and, alternatively, Phillips in view of Hirayama.

Insofar as the rejections are applicable to amended claims 1, 5, and 10, applicants respectfully traverse these obviousness rejections because Hirayama or Phillips, whether considered alone or in combination with each other, fails to teach or suggest the claimed invention.

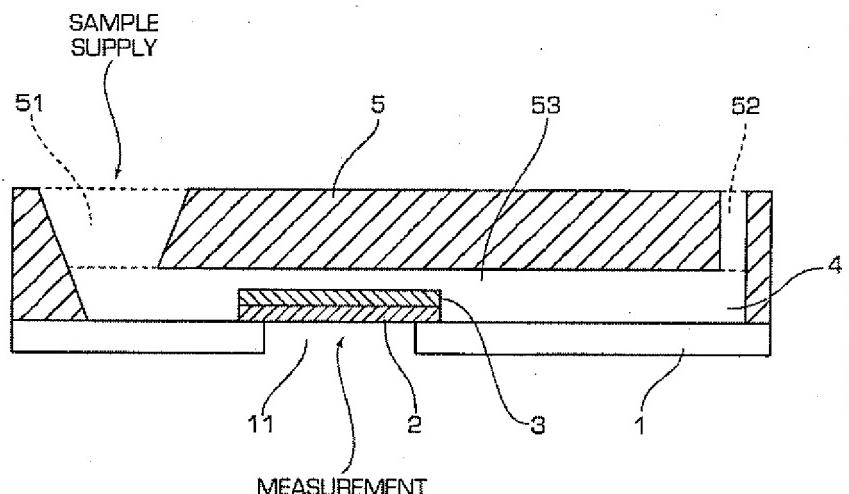
Each of the independent claims 1, 5, and 10 has been amended to recite specific features of a reagent pad for each of the test device and system claimed. In particular,

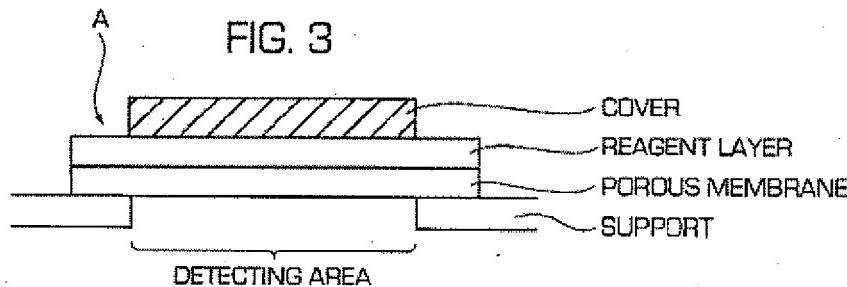
the claims recite, *inter alia*, that the reagent pad is affixed to a bottom surface of a support and in direct contact with a through aperture, and at least a portion of the bottom surface of the support disposed about the aperture has a reflectivity of less than about 12 percent at between about 600 and 730 nm.

Hirayama or Phillips, whether considered alone or in various combinations with each other, fails to show and describe all of the claimed features, as provided in amended claims 1, 5, and 10. Specifically, no reflectance value or frequency range was given for any surfaces of support 1 in Figure 1 of Hirayama. Phillips, on the other hand, fails to describe any reflectance for the surface of the test strip 10. Absent applicants' present disclosure, one of ordinary skill would not have been motivated to modify either Hirayama or Phillips or both to arrive at a specific reflectance on the bottom surface proximate the aperture of the claimed support. Consequently, applicants respectfully submit that a *prima facie* case of obviousness has not been established pursuant to MPEP 2143.03 (Rev. 5, August 2006) because all of the claimed features have not been taught or suggested by the cited prior art as neither Hirayama nor Phillips show, describe or suggest that the bottom surface proximate an aperture of a support for a reagent pad be provided with a specific reflectance and frequency range.

Applicants further submit that the proposal by the Office to eliminate the chamber 53 in Figure 1 of Hirayama (reproduced at right) would not achieve the claimed features of amended claims 1, 5, or 10 because any elimination of the chamber 53 would not likely involve placing the sample receiving hole 51 directly in contact with the reagent layer 3.

FIG. 1





In fact, Hirayama has shown that while the chamber 53 of Figure 1 can be eliminated, as shown in Figure 3 (reproduced at left), there is apparently no need for the holes 51 and 52 or

even to have the reagent layer be in contact with any of the holes because a liquid sample is spotted at location "A" (col. 3, lines 51-60). Applicants believe that the reason for the elimination of holes 51 and 52 in Figure 3 is because the embodiment in Figure 1 of Hirayama utilizes a supply hole 51 spaced at a distance from the reagent layer 3, which apparently relies upon capillary action via air exhaust hole 52 to transport blood sample to the reagent layer 3. Once the chamber 53 was eliminated, as in Figure 3, applicants submit that there was no need for the holes 51 and 52 in Figure 3 as the blood sample was deposited directly on the reagent layer at location A. Consequently, Figure 3 of Hirayama demonstrates that, while the proposed modification by the Office to eliminate chamber 53 in Figure 1 would be possible, such modification would not have arrived at the claimed invention as there would be no need for hole 51 in Figure 3. Thus, the proposed elimination of chamber 53 in Figure 1 fails to provide all of the claimed features, specifically that of a reagent pad directly contacting an aperture of a support surface having a claimed reflectance value.

The Office has further concluded that the claimed reflectance value is an optimization of a "result effective variable" and therefore obvious for one of ordinary skill to utilize with Phillips or Hayarama. Applicants also respectfully traverse this conclusion.

As noted in the MPEP, only "results-effective variables" in the prior art can be optimized. *See, MPEP at 2144.05(II)(B)(p. 2100-149).* That is, a "result-effective variable" is one that achieves a recognized result in the prior art. Such variable must be

first identified before the variable can be said to be "optimizable." Phillips or Hayarama fails to identify that the reflectivity of the bottom surface of a strip 10 in Phillips or support 1 of Hayarama proximate a reagent pad is a result-effective variable. While Phillips has identified a porous matrix pad 11 as having a desired reflectance (Phillips at col. 6, lines 12-20), Phillips fails to show or describe that the reflectance of the bottom surface of strip 10 proximate the aperture and reagent pad 11 is critical to the function of the test strip such that optimization of the reflectance of such surface may be required.

Similarly, Hayarama fails to describe any reflectance for the support 1 because Hayarama was apparently concerned with reflectance of the cover 5 rather than that of the support 1. Because the reflectance of the bottom surface of the strip proximate the reagent pad has not been identified by Phillips or Hayarama as a result-effective variable, there was no "variable" in Phillips or Hayarama that one of ordinary skill could "optimize." Accordingly, claims 1, 5, and 10 are patentable over Hirayama or Phillips, whether considered alone or in combination as primary or secondary references with each other.

Claims 13-16 have been added to particularly point out and distinctly claim the subject matter of applicants' invention. Support for claims 13-16 is provided in the originally-file application at, for example, page 3, lines 23-30.

Because dependent claims 3, 4, 6-9 and 11-12 depend respectively from allowable claims 1, 5, and 10, the dependent claims are also allowable over the proposed combination of references for this reason, as well as for reciting other features. Similarly, claims 13-16 depend respectively from allowable claims 1 and 5 and therefore these claims are also allowable for this reason, as well as for reciting other features.

## CONCLUSION

Applicants respectfully request that, in light of the amendments and explanations above, the Examiner reconsider and withdraw his rejections. Applicants respectfully submit that the claims are in condition for allowance. In the event that minor claim amendments are necessary to meet formal requirements, applicants invite the Examiner to telephone the undersigned so that issuance can be expedited.

The Commissioner is hereby authorized to charge any required fees due in connection with this submission, including petition and extension of time fees, and to credit any overpayment to Deposit Account No. 10-0750 (Docket No. LFS0123US/KQT) (Johnson & Johnson).

Respectfully submitted,

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